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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/994,468 12/19/97 LYMAN

S 2813-L

LAW DEPARTMENT
IMMUNEX CORPORATION
51 UNIVERSITY STREET
SEATTLE WA 98101

HM22/0229

EXAMINER

KERR, J

ART UNIT

PAPER NUMBER

1633

10

DATE MAILED:

02/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/994,468

Applicant(s)
Lyman et al.

Examiner
Janet M. Kerr

Group Art Unit
1633



☒ Responsive to communication(s) filed on Dec 7, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Response to Arguments

Applicants' Request for Reconsideration, has been entered.

Claims 1-8 remain pending.

With regard to the numbering of the claims, it should be noted that the only claims initially submitted with application serial number 08/994,468 were claims 36 and 49. Claims 50-55 were subsequently submitted with Paper No. 2, filed on 12/19/97. As the instant application is a continuation of application serial number 08/738,628 (as set forth on page 1, first paragraph of the instant application), should applicants wish to maintain these claim numbers, then applicants should submit a copy of the claims which had been pending in application serial number 08/738,628, with a request for cancellation of the appropriate claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lyman *et al.* (Cell, 75:1157-1167, 1993) for the reasons of record and the reasons below.

Lyman *et al.* disclose a stem cell expansion media comprising cell growth media, flt3-ligand, and steel factor, and a method of expanding hematopoietic cells comprising contacting the cells with flt3-ligand alone or in combination with steel factor in amounts sufficient to cause hematopoietic cell expansion (see, e.g., page 1165, under the section entitled "Hematopoiesis Assays", and pages 1161-1162, under the section entitled "Murine flt3 Ligand Stimulates the Proliferation of Human CD34-Positive Bone Marrow Cells).

Thus the method and stem cell expansion media of Lyman *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lyman *et al.* (Cell, 75:1157-1167, 1993), taken with Heimfeld *et al.* (WO 93/08268, 1993), and Hoffman *et al.* (WO92/18615, 1992) for the reasons of record and the reasons below.

Lyman *et al.* (Cell) disclose a stem cell expansion media comprising cell growth media, flt3-ligand, and steel factor, and a method of expanding hematopoietic cells comprising contacting the cells with flt3-ligand alone or in combination with steel factor in amounts sufficient to cause hematopoietic cell expansion (see, e.g., page 1165, under the section entitled "Hematopoiesis Assays", and pages 1161-1162, under the section entitled "Murine flt3 Ligand Stimulates the Proliferation of Human CD34-Positive Bone Marrow Cells).

The above reference does not disclose a medium formulation containing flt3-ligand and other claim-designated growth factors. However, Heimfeld *et al.* disclose a cell culture medium for expanding hematopoietic stem cells which comprises cell growth media, and growth factors such as IL-1, IL-3, IL-4, IL-6, IL-7, SF, GM-CSF, G-CSF, M-CSF, etc. (see, e.g., page 5, lines 14-29). Similarly, Hoffman *et al.* disclose a medium formulation for expanding hematopoietic stem cells comprising growth factors selected from IL-1, IL-3, IL-6, GM-CSF, GM-CSF/IL-3, as well as other growth factors (see, e.g., page 14, Table I, page 23, Table IX). As the growth factors disclosed by Heimfeld *et al.* are similarly disclosed by Hoffman *et al.*, all of which are known to stimulate expansion of hematopoietic stem cells, one of ordinary skill in the art would

have had a high expectation of successfully expanding hematopoietic stem cells in a culture medium comprising flt3-ligand and an additional growth factor.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a medium formulation containing flt3-ligand and a growth factor such as SF, GM-CSF, IL-1, IL-3, G-CSF, EPO, or GM-CSF/IL-3, as formulations containing flt3-ligand in combination with other growth factors are known in the art to be suitable for expanding hematopoietic stem cells as taught by Lyman *et al.*, or by Hoffman *et al.* Moreover, it would have been obvious and well within the purview of the skilled artisan to substitute one growth factor for another, as all of the reference and claim-designated growth factors are known in the art to stimulate proliferation of hematopoietic stem cells. Thus, one of ordinary skill in the art would have had a high expectation of successfully expanding hematopoietic stem cells in a medium formulation containing flt3-ligand and other growth factors, in view of the disclosures of Lyman *et al.*, Hoffman *et al.*, and Heimfeld *et al.*, that the claim-designated growth factors stimulate hematopoietic stem cell expansion.

Thus the claimed invention as a whole was clearly *prima facie* obvious at the time the claimed invention was made especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Applicant's arguments filed 12/7/99 have been fully considered but they are not persuasive. Applicants argue that the Lyman *et al.* reference has been cited improperly as the present application has an effective filing date that is at least as early as 8/25/93 (the filing date of Application Serial No. 08/111,758) or 12/3/93 (the filing date of Application Serial No. 08/162,407). Applicants indicate that examples 7 and 8 of the present application are present in Application Serial No. 08/111,758, and that examples 7-9 of the present application are present in Application Serial No. 08/162,407. It should be noted, however, that these examples are directed to an *in vitro* method of expanding hematopoietic cells in the presence of flt3-ligand and the growth factors IL-3 and IL-7. There is no disclosure of compositions comprising any of the other

claim-designated growth factors. As the broad claims 1 and 2, embrace growth factors other than IL-3 and IL-7, and as there is no description of any of the other growth factors claimed in the instant invention, there is no support for the claimed growth factors in Application Serial Nos. 08/111,758 and 08/162,407. Therefore, the instant application is not entitled to the earlier filing dates of Application Serial Nos. 08/111,758 and 08/162,407. Thus, the use of the Lyman *et al.* reference is not improper and the rejections are maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, and 10 of copending Application No. 08/399,404. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of co-pending application Serial No. 08/399,404 are directed to a kit which comprises a cellular growth medium and a growth factor, wherein the growth factor can be selected from GM-CSF, G-CSF, IL-1, IL-3, IL-6, TPO, EPO, flt3-ligand, SF, and a GM-CSF/IL-3 fusion protein. As the composition and method of using the composition in the instant application are encompassed in the kit and the intended use of the kit, the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 12/7/99 have been fully considered but they are not persuasive.

Applicants argue that the pending claims of the instant invention, directed to a cell expansion medium, and the claims of copending Application Serial No. 08/399,404, directed to a kit containing the cell expansion medium, are different inventions. This is not persuasive as the claims in both applications comprise the same composition, i.e., a cell expansion medium which can comprise the same components. Thus, the inventions are not patentably distinct inventions. In addition, applicants' arguments that it is applicants' opinion that the claims of the instant application are allowable, and as such, the obviousness-type double patenting rejection should be withdrawn and the determination of obviousness-type double patenting taken up with Application Serial No. 08/399,404, are not persuasive as the claimed subject matter is not allowable for the reasons set forth in the 35 U.S.C. 102(b) and 35 U.S.C. 103(a) rejections above.

Sequence Compliance

As applicants have provided a statement requesting transfer of the sequence listing from Application Serial No. 08/162,407, and have indicated that the sequence listings are identical, the notice to comply with the requirements of 37 CFR 1.821 through 1.825 has been withdrawn.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

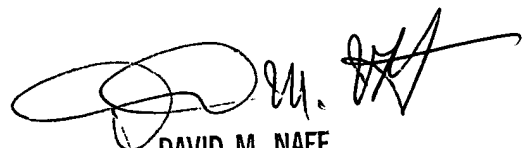
A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Michael Wityshyn, Supervisory Primary Examiner of Art Unit 1651, at (703) 308-4743. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651